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April 25, 2001

3M

Mr. Charles Auer
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460

Re: Serum Half-Life of Perfluorooctane Sulfonate

Dear Mr. Auer:

This will summarize the discussion during our conference call on March 19, 2001 with you, Oscar Hernandez, Michael Santoro and me regarding new information obtained as part of the ongoing serum half-life study on PFOS.

As you know, 3M has been attempting to calculate a half-life for perfluorooctane sulfonate (PFOS) in serum of retired workers. We have previously reported on two interim data sets. 3M has continued to study this issue. Currently available data are difficult to interpret. They do not corroborate our prior calculations.

In January 1999, 3M provided EPA with limited data from 3 workers indicating a half-life for PFOS in retired workers' serum of approximately 1,400 days. 3M had in progress a larger study, and on July 15, 2000, submitted the first interim report on serum half life of PFOS among 27 retired employees. These employees had worked at 3M's Decatur, Alabama and Cottage Grove, Minnesota manufacturing plants.

This initial analysis of the 27 retirees used data points collected in November 1998, May 1999 and November 1999, designated t_0, t_1 and t_2. Using a one-compartment model, the mean serum half life determined for 18 of the 27 employees was 303 days (range 139 – 640 days). The remaining 9 employees either had less than three data points or did not show a trend. The 303 days was near the serum half life that was initially reported for cynomolgus primates (274 days). Although we were aware of several limitations in this study, 3M considered the interim data to be an improvement over our previous estimate, based on only 3 employees, and using varying analytic techniques for determining PFOS. However, the Interim Report advised caution in interpreting the limited data set.

Serum was collected in May 2000 for a fourth data point (t_3). Initial analysis was returned several months later and showed results inconsistent with those expected. This caused us to reexamine of sources of error in the laboratory measurement. The analytic technique exhibits variability of 20 to 30% when the same sample is

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measured at different time points. The best way to reduce this variability is to run all samples from one subject during one analytic run. Random errors represent another type of error, and multiple analysis of the same sample can be used to reduce errors from this source.

Nine of the 27 subjects, representing a range of PFOS values, were selected for reanalysis. Triplicate analysis was done for all time points (t_0 through t_3). All samples for each subject were analyzed during one analytic run. In this way, controllable sources of variability were reduced. Preliminary analysis of these data does not corroborate the range for serum half life reported in the first Interim Report. The data from these nine subjects for t_0 through t_3 suggest a minimum half life near 1500 days, but we are still exploring various issues that confound interpretation of the data.

Other factors complicating assessment of the serum half-life in retired workers may include the possible presence of other fluorochemicals from occupational exposure that may be metabolized to PFOS during the study; ongoing non-occupational exposure during the study; or difficulty deriving average values if the elimination kinetics are concentration-dependent, since the workers began the study with varying levels. At this point, the caution admonished in both 3M's Interim Report and the October 2000 draft OECD Initial Assessment is appropriate. Neither the current calculation nor prior values should be considered conclusive estimates.

We plan to submit a second interim report in the summer of 2001. Our plan after that, however, is to collect data for a period of at least two years and possibly longer before doing any more analysis, which will then be done in such a way as to reduce laboratory variability as much as possible.

Although this type of study continues to carry many limitations, it remains a good opportunity to measure human serum half life, albeit at concentrations many times higher than those observed in non-occupationally exposed individuals.

Please do not hesitate to contact me if you have any questions.

Very truly yours,

Larry R. Zobel MD, MPH /jmc

Larry R. Zobel, M.D., M.P.H.
Medical Director

c: Mr. Oscar Hernandez
Mr. Michael Santoro